

Out of range:

Audit of anticoagulation management in secondary care in England



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Anticoagulation UK

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Foreword

Anticoagulation therapy is indicated for a wide range of conditions including atrial fibrillation (AF), prosthetic heart valves, venous thromboembolism treatment and prevention, thrombotic disorders, and other cardiac conditions. AF accounts for the largest cohort of patients within most anticoagulation services. Many of the core elements of a high-quality anticoagulation service for patients with AF are applicable to anticoagulation care in general.¹

AF is the most common sustained cardiac rhythm disorder and a known major risk factor for stroke - the third leading cause of death in England.^{2,3} As well as the devastating effect on patients, their families and carers, AF-related stroke also has significant cost implications for the health system regarding immediate and long-term care.⁴ It is estimated that AF-related illness, including strokes, costs the NHS over £2.2 billion each year.⁵

A range of guidelines are available for both commissioners and healthcare professionals on managing AF.^{1,6,7,8,9} Despite a raft of guidelines for identifying and treating patients with AF, there is no standard specification for what constitutes an exemplar anticoagulation service, and models of care vary across the country across various settings in the healthcare system including, outpatient clinics in secondary care, GP practices and community pharmacy-led services.

These different approaches have led to concerns regarding variation and the quality and safety of anticoagulation services.¹ The lack of standardisation means it is important to gather information on how well patients with anticoagulation needs are being managed and supported by individual services to enable continuous and focused quality improvement. This report aims to bring together information from NHS Trusts on the processes they have in place to support optimal anticoagulation patient care and outcomes in secondary care.

Much more still needs to be done to improve the detection and treatment of AF. NHS England and Public Health England have identified the scale of the benefits that can be realised through coordinated and focused quality improvement programmes. They estimate that over 14,000 strokes in England could be avoided over three years, if everyone with AF was diagnosed and received appropriate anticoagulation therapy, and over £240m in financial savings could be delivered by optimising AF treatment.^{10,11} It is important that there is clear accountability across public health, NHS and social care for achieving these ambitions.

We hope that this report will complement the work being undertaken through these improvement strategies at national and local levels to increase the proportion of at-risk patients being identified and treated appropriately. We stand ready to work with all NHS organisations responsible for planning and delivering anticoagulation services to ensure that all patients are optimally protected against AF-related stroke and receive the right information, support and access to effective treatment in England, and the rest of the UK.

Eve Knight
Chief Executive, Anticoagulation UK

1. Summary of findings



Up to **37,878** Warfarin patients identified as having sub-optimal anticoagulation control and therefore at **an increased risk of stroke or bleeding**¹²

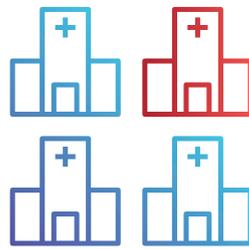


29,305 Warfarin patients recorded as spending less than **65 per cent of time** in therapeutic range (TTR) putting them at an increased risk of stroke¹²

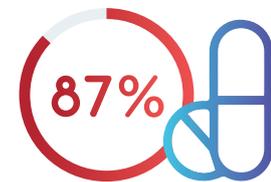
Up to **42%** of NHS Trust respondents **do not routinely collect data** on the time in therapeutic range (TTR)¹³ and the international normalised ratio (INR) measures¹⁴ of patients taking warfarin, so are potentially unaware of the number of patients in their care who are at **increased risk of stroke or bleeding**



13 times a year the average AF patient, taking warfarin, will require an appointment with their GP or anticoagulation clinic to have their anticoagulation monitored¹⁵



Almost a quarter of responding Trusts have no patients who are **self-monitoring** their warfarin¹⁶



87% of responding Trusts have no patients who are **self-managing** their warfarin¹⁶

6 root cause analyses conducted for adverse events (AEs) relating to anticoagulation treatment, in the last 12 months, were flagged by Trusts responding to the FOI. However, the reality **will be a lot higher** given the number of sub-optimally treated warfarin patients, meaning such **incidents are under recorded**¹⁷



62% of responding Trusts have **no written clinical protocols** in place for reassessing anticoagulation in AF patients who have **poor anticoagulation control**¹⁸



Only **38%** of responding Trusts **provide more than leaflets** to patients to support their understanding of AF and adherence to treatment¹⁹

1 in 10 responding Trusts provide no information, education or support materials for AF patients in their care¹⁹



This report gathers information obtained through Freedom of Information (FOI) Act requests submitted in July 2017 to 149 secondary care NHS Trusts in England. The findings and analysis are based on the Trusts' responses to the FOI request, which were received by the end of August 2017.

In total, 91 Trusts were able to provide a full or partial response to the FOI request. The report is not intended to directly compare anticoagulation services, but to

increase understanding about the policies and processes used by providers of anticoagulation service in secondary care, and identify what more can be done to ensure all patients with AF receive safe and effective treatment and support after being diagnosed.

Anticoagulation UK has been supported to undertake this project, with financial support from Bayer UK. The content of the report has been reviewed by Bayer UK to ensure compliance with the ABPI Code of Practice.

2. The need to improve AF-stroke prevention and anticoagulation care

Reducing the number of avoidable strokes caused by AF with better detection and management has been identified as a major area for improvement by the NHS.²⁰ It is estimated that there are over 1.4 million people with AF in England, but approximately a third are undiagnosed and are therefore not being offered treatment to reduce their risk of stroke.²¹

AF-related strokes are largely preventable through effective and well-managed anticoagulation therapy; however, under-treatment is common to the extent that only half of people with known AF who then suffer a stroke have been anticoagulated before their stroke.²² The extent of this problem represents a major quality of care issue, and more concerted action is needed to significantly reduce the proportion of AF patients being admitted to hospital following a stroke who are not being treated in line with NICE clinical guidelines.

Although there are valid scenarios where it may not be clinically appropriate for a patient to be given an anticoagulant, the National Clinical Directors for Stroke and Cardiovascular Disease Prevention have made clear that failure to prescribe an important treatment should be seen as an error that is equally as serious as prescribing the wrong treatment.⁹

Recommendation: All national policy documents related to the prevention of AF-related stroke should be updated to make explicit that failure to prescribe an effective anticoagulant should be regarded as a 'never event'

What is an atrial fibrillation-related stroke?

Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate.²⁸ This can lead to blood clots forming in the upper chambers of the heart (the atria) that can then enter the general circulation and block arteries in the brain, causing a stroke.²⁹ AF is thought to cause one-in-five strokes each year in England and, if left untreated, people with the condition are five to six times more likely to suffer a stroke than people with a regular heart rhythm.^{30,31}

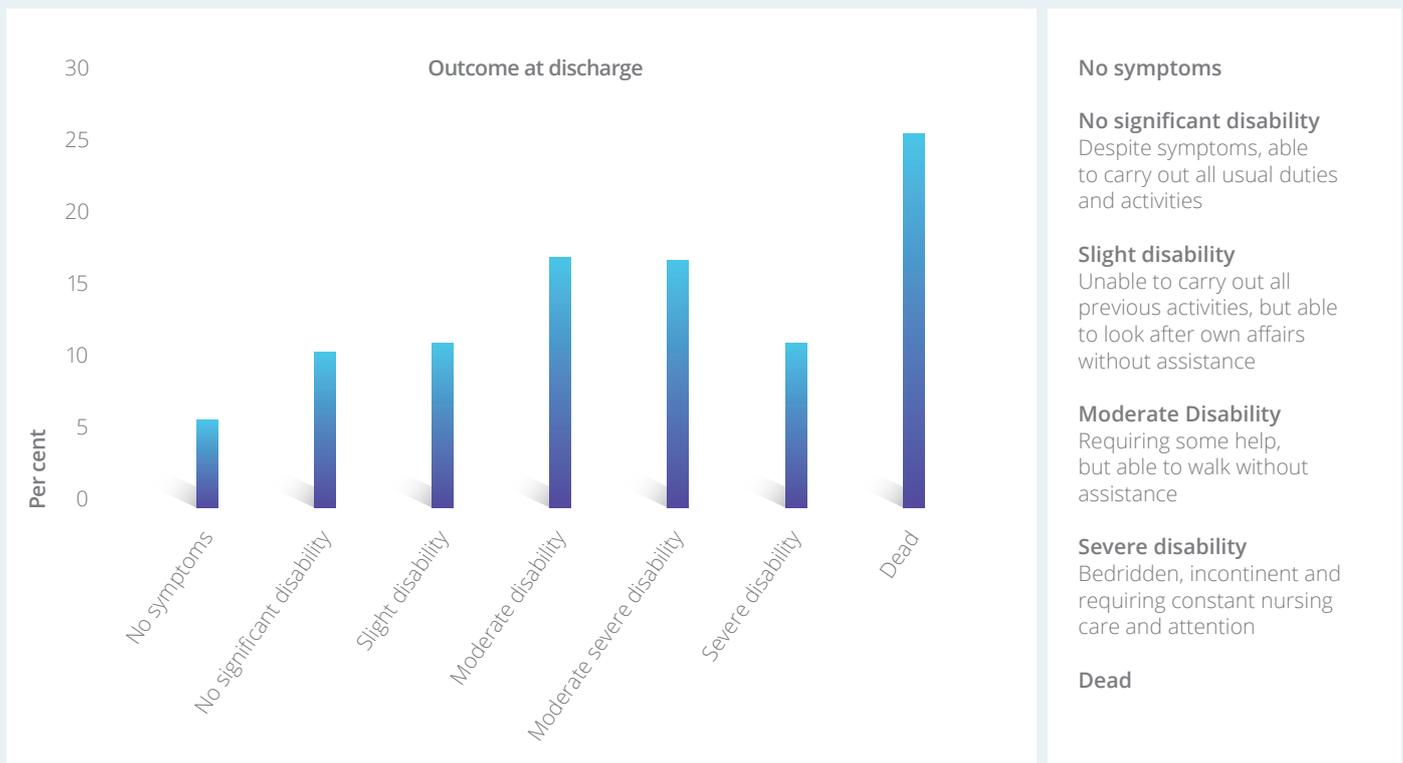
A manual pulse check is a good indicator of AF.³² Opportunistic screening of those aged over 65 has been identified as a cost-effective way of detecting underdiagnosed AF.³³ Ensuring pulse checks are routinely provided in flu vaccination clinics and community pharmacies, as well as part of blood pressure checks, would help to reduce the number of people with AF at risk of stroke who are unprotected.

What does good AF-stroke prevention look like?

Anticoagulation reduces the risk of stroke in people with AF by two thirds.²² The National Institute for Health and Care Excellence (NICE) recommends people with AF who are at risk of AF-related stroke should be offered an anticoagulant therapy - either warfarin or a direct oral anticoagulant (DOAC).⁶ However, national clinical audit data collated by the Royal College of Physicians (RCP) reveals that in practice this is not happening consistently with many AF patients receiving no, or sub-optimal, stroke prevention therapy.²³

During 2016-17, there were 14,840 people admitted to hospital with AF-related strokes in England.²³ Almost half of these AF-related stroke patients admitted were not receiving appropriate anticoagulation therapy despite being known to have AF before their stroke.²³ A further 20 per cent occurred in people who were being treated with an antiplatelet medicine only,²³ which is explicitly not recommended by NICE.⁶ The chart below shows the poor outcomes for those patients identified with AF but not receiving anticoagulation with over a quarter of patients (1,838 - 26.1 per cent) of AF-related stroke patients who were not anticoagulated dying in hospital, and almost half (3,230 - 45.8 per cent) discharged with a moderate to severe disability.²⁴

Outcome at discharge from inpatient care of people with AF who were not on anticoagulation prior to stroke²⁴



Evidence also shows that even when diagnosed, inadequate treatment is also common. It is widely recognised that large numbers of patients do not receive appropriate anticoagulants or have poor anticoagulation control.²² In recognition of these challenges, a series of national programmes have been formed to improve the identification and management of AF patients at high-risk of stroke:

- **Size of the Prize:** NHS England and Public Health England focused on delivery at-scale improvement in the secondary prevention of cardiovascular disease, and suggest that optimising AF treatment could prevent 14,000 strokes and save £240 million over three years²⁵
- **NHS RightCare CVD prevention pathway:** An evidence-based pathway developed to support local health economies to concentrate their improvement efforts on where there is greatest opportunity to address variation and improve population health. The ‘high value intervention in atrial fibrillation’ pathway seeks to address the issue that over half of AF patients are untreated or poorly controlled²⁶
- **CVD area profiles and primary care intelligence packs:** To support decision making, Public Health England provides commissioners and health professionals profiles on the impact of CVD on their local population.²⁷ The intelligence packs are resources for stimulating local conversations about quality improvement in primary care, which is central to improving outcomes in CVD because it is where much prevention, diagnosis and treatment is delivered²²

Recommendation: NHS England and Public Health England should publish annual data on progress in increasing the proportion of AF patients who are offered and started on appropriate NICE-approved anticoagulant treatment

3. Supporting patients to choose the right anticoagulation treatment to meet the needs and preferences of patients

The risk of an AF-related stroke for people with AF can be substantially reduced through effective anticoagulation therapy to prevent the formation of clots in the heart. Clinical guidelines recommend people with AF who are at risk of stroke should be offered either warfarin or a direct oral anticoagulant (DOAC) where clinically appropriate.^{6,34} The same guidelines also make clear that aspirin should no longer be offered as a standalone treatment option to patients for stroke prevention.⁶

Warfarin has been an established treatment option for reducing the risk of AF-related stroke for 60 years. When used appropriately, warfarin is effective in stroke prevention, reducing the risk of AF-related stroke by 64 per cent.³⁵ While suitable for some patients, warfarin has a narrow therapeutic window in which it is safe and effective. This means that patients require regular monitoring and dose adjustments to reduce their risk of stroke and adverse events such as bleeding.⁹ Maintaining safe and effective anticoagulation levels for warfarin is complicated further by interactions with a range of food, alcohol and other medications.³⁶

In recent years, DOACs – apixaban, dabigatran, edoxaban and rivaroxaban – have been approved by NICE as a cost-effective, alternative treatment options to warfarin for AF-related stroke. DOACs were specifically developed to overcome some of the limitations associated with warfarin by providing predictable and stable anticoagulation levels which do not require routine monitoring, regular dose adjustments and dietary changes which may be preferable for many patients from a clinical and lifestyle perspective.³⁷

Overall, warfarin continues to be the most commonly used anticoagulation therapy for AF – with around two thirds of all anticoagulant prescription for warfarin, compared to a third for DOACs. Usage of DOACs is increasing nationally, although uptake has been variable across different parts of the country.³⁸

Enabling patients to choose the anticoagulation treatment which is right for them

It is vital that all recommended treatment options for stroke prevention in AF are available and offered to all patients where clinically appropriate, with no restrictions on the availability of certain treatment options. Critically, all AF patients who would benefit from anticoagulation therapy should be supported to make an informed choice about which proven licensed therapy is right and clinically appropriate for them based on their individual needs and preferences.¹

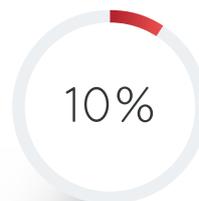
The way that anticoagulants work to prevent clots, by interrupting the process involved in the formation of blood clots, means there is also an inherent bleeding risk with a heightened risk of causing harm when used in error.³⁹ For most people the benefit of anticoagulation outweighs the bleeding risk; however, prior to the initiation of any anticoagulation therapy, it is vital that stroke and bleeding risk are assessed in each individual patient to determine the most appropriate treatment strategy.⁶

Anticoagulation service providers should address the following aspects to ensure patients are sufficiently informed and supported when considering their treatment options:⁴⁰

- **Information and awareness:** All patients, and healthcare professionals responsible for their care, should have accessible information on how to use medicines safely and effectively, including identifying and managing side effects, monitoring treatment, interactions with other medications, food and alcohol, monitoring requirements and lifestyle restrictions
- **Dosing and administration errors:** It is important that patients and health and social care staff realise the importance of high adherence, and that prescribers select the correct dose and dosing interval for the indication. Omitting or delaying doses can lead to a reduction in anticoagulation effect, resulting in thrombosis
- **Interactions, contraindications and warnings:** Care should be taken when considering prescribing any anticoagulant to a person with other conditions, procedures or concomitant treatments that may increase the risk of major bleeding

The current review of NICE clinical guidelines for AF provide a timely opportunity to reinforce the need for all anticoagulation treatment decisions to be made by patients, in partnership with their healthcare professional, following a comprehensive education and consultation. Specifically, this should include information on the advantages and disadvantages of all treatment options, and be followed by an ongoing package of patient monitoring, review, education and support.

Responses to the audit questions revealed significant differences across Trusts in the range and quality of information, education and support materials provided for AF patients to support their understanding of the condition and treatment:



- **10 per cent of Trusts** indicated that they provide no information, education and support materials for AF patients¹⁹



- **15 per cent of Trusts** reported providing patients with the standard 'yellow' booklet to identify they are taking an oral anticoagulant.¹⁹ This book is a key material which contains generic information for all patients taking anticoagulation medicine and includes key safety information, including dietary advice, dosage information and emergency contact details⁴⁰



- **38 per cent of Trusts** providing support indicated that they provided leaflets or patient information booklets, with some directing patients to the websites of recognised patient groups¹⁹

Recommendation: The NICE clinical guideline (CG180) should be updated to include a clear specification of the information, education and support materials that anticoagulation service providers should be routinely offering to AF patients

4. Enabling good anticoagulation control and effective AF-related stroke prevention

Evidence highlighting the scale of undetected, untreated and poorly managed people with AF, together with the increased number of anticoagulation treatment options following the emergence of DOACs, has led to a raft of best practice guidelines and commissioning support tools for AF to help with service planning and provision.^{1,6,7,8,9} These resources underline the need for all anticoagulation services to have the necessary protocols and pathways in place to support patients during the initiation and maintenance of their treatment with warfarin and DOACs.

Maintaining good anticoagulation control

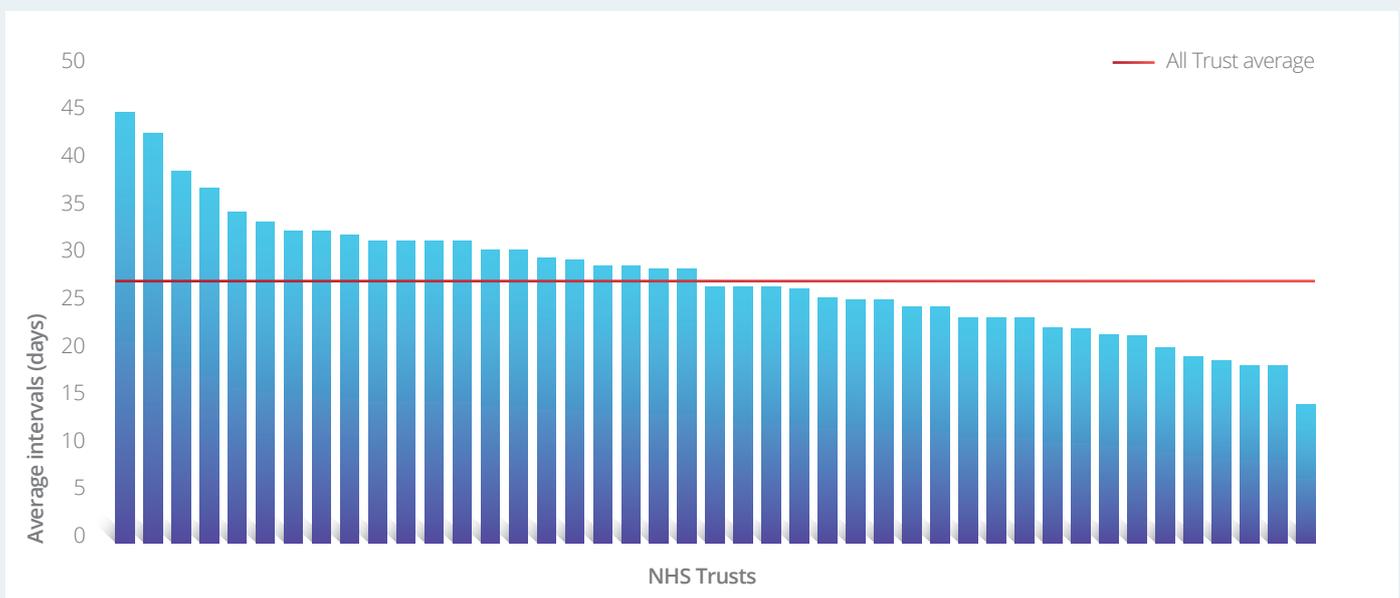
Warfarin has a narrow therapeutic window, and is affected by dietary intake of food and alcohol, as well as other medication, so requires regular blood test monitoring.³⁶ The frequency of monitoring for warfarin patients is determined by the stability of each patient's international normalised ratio (INR) which indicates how long it takes for the blood to clot. The recommended target INR for patients with AF is between 2 and 3. The risk of stroke increases substantially when the INR is below 2, and the risk of bleeding increases above an INR of 3.

Ensuring that the INR remains in the therapeutic range for as long as possible is vital. The minimum acceptable time in therapeutic range (TTR) is 65 per cent.¹ It is estimated that even well-monitored warfarin patients are outside of therapeutic range approximately one third of the time meaning they are at an increased risk of stroke.⁴¹

Monitoring, through regular blood tests, usually takes place at a hospital clinic or the patient's GP surgery. For most patients, monitoring takes up to one hour, including travel to and from the appointment. The time required from a patient for monitoring could range from six hours or less in a year, to 52 hours a year, depending on how stable their INR is.⁴²

From the 51 per cent of Trusts that were able to provide data on the frequency of INR tests for warfarin patients, the average interval between blood tests was 27 days, meaning that patients were monitored 13 times a year.¹⁵ The need for routine anticoagulation monitoring adds significantly to the cost of treatment and places additional capacity pressures on warfarin clinics.⁴³

Average days between blood tests for anticoagulation patients treated with warfarin by trust¹⁵



Self-monitoring and self-management

Regular anticoagulation monitoring with warfarin often means frequent visits to anticoagulation clinics for patients to have their levels of anticoagulation monitored and dose adjustments. This can be problematic for people in full-time employment who find it hard to take time off work, and the elderly who might find it hard to attend a clinic due to co-morbidities or mobility issues.

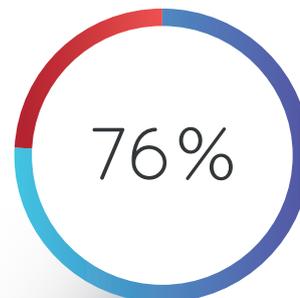
Self-monitoring and self-managing, using approved point-of-care test (POCT) devices, offers a more convenient solution for some patients. It reduces the need for regular hospital or clinic visits, and can improve anticoagulation control and risk of adverse bleeds. The ability to self-monitor and/or self-manage allows warfarin patients to measure their blood clotting themselves and change their dose in agreement with their healthcare professional. All anticoagulation services should have procedures and protocols in place to meet the needs of AF patients who want, and are able, to self-monitor and/or self-manage their warfarin anticoagulation, including information, education and training.

24 per cent of responding Trusts have no patients at all self-monitoring their warfarin anticoagulation.¹⁶

In Trusts where patients are self-monitoring, approximately 14 in every 1,000 patients identified by the audit are self-monitoring their anticoagulation and approximately only four in every 10,000 patients are self-managing their dosing.^{16,44}

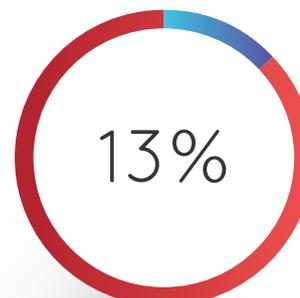
Furthermore, only 13 per cent of Trusts have patients self-managing their anticoagulation.¹⁶ 10 Trusts reported not offering either self-monitoring or self-management to patients in their care.¹⁶

Trusts with patients self-monitoring their warfarin anticoagulation¹⁶



● Yes
● No

Trusts with patients self-managing their warfarin anticoagulation¹⁶



● Yes
● No

Recommendation: For all suitable warfarin patients, it should be recorded in their patients notes whether they have been offered to self-monitor and/or self-manage their anticoagulation, and where these have not been offered, an explanation should be provided

5. Measuring safe and effective anticoagulation

Even when people with AF are correctly diagnosed and treatment is started, strokes still can and do occur, often due to poor quality of anticoagulation control and poor adherence to treatment.⁹ Sub-analysis of national audit data shows that 83 per cent of stroke patients with known AF, who were prescribed an anticoagulant, were found to have inadequate control⁴⁵ and, therefore, at increased risk of stroke or bleeding.

It is recommended that for people who are taking an anticoagulant, a review of their need for anticoagulation and the quality of anticoagulation should take place at least annually, or more frequently if clinically relevant events occur affecting anticoagulation or bleeding risk. The Quality Outcomes Framework (QOF) may be updated in 2017/18 to incorporate a dedicated indicator which supports regular reviews of patients receiving anticoagulation. This would support the collection of data on the number of AF patients who are treated with an anticoagulant and have had a primary care review in the last 12 months.⁴⁶

AF-stroke prevention will be suboptimal if anticoagulation treatment is poorly controlled. As warfarin remains the most commonly prescribed anticoagulant therapy for AF and requires frequent monitoring to assess its safety and efficacy, collecting and reviewing clinical data for anticoagulation services at both patient and practice level is critical to maintaining an overall picture of how patients are being managed at a population level but also assessing the care of individual patients to evaluate whether they are being optimally managed to protect them against stroke and minimise their bleeding risk.

Assessing the quality of anticoagulation management

For most warfarin patients, the target INR is 2.5, with an acceptable range between 2.0 and 3.0, with some exceptions in patients with mechanical heart valves and other health condition.⁴⁷ Calculating the percentage of time in therapeutic range (TTR) for patients on warfarin is vital to determine the clinical benefit of the treatment and identifying whether they are at increased risk of stroke or bleeding. TTR should be calculated over a maintenance period of six months, excluding the first six weeks following initiation and recorded at each visit to an anticoagulation clinic.

The target TTR should be as high as possible. Patients with a TTR below 70 per cent do not receive the full benefits of anticoagulation, and those below 40 per cent receive no benefit at all.⁴⁷ For those below 65 per cent, an assessment should be made as to whether warfarin is the most appropriate treatment for them. NICE clinical guidelines specify the following a list of indicators for poor warfarin control:⁶

- **Two INR values higher than 5.0** within the past six months (increased bleeding risk)
- **One INR value higher than 8.0** within the past six months (increased bleeding risk)
- **Two INR values less than 1.5** within the past six months (ineffective anticoagulation)
- **TTR less than 65 per cent** (ineffective anticoagulation)

Data obtained through responses from NHS Trusts on INR values and TTRs revealed that there are at least 37,878 patients in England recorded as having sub-optimal warfarin control.¹² The majority of these are patients are not being adequately protected against the risk of stroke, particularly those recorded as having a TTR of less than 65 per cent.

Indicator^{6,12}

Number of patients

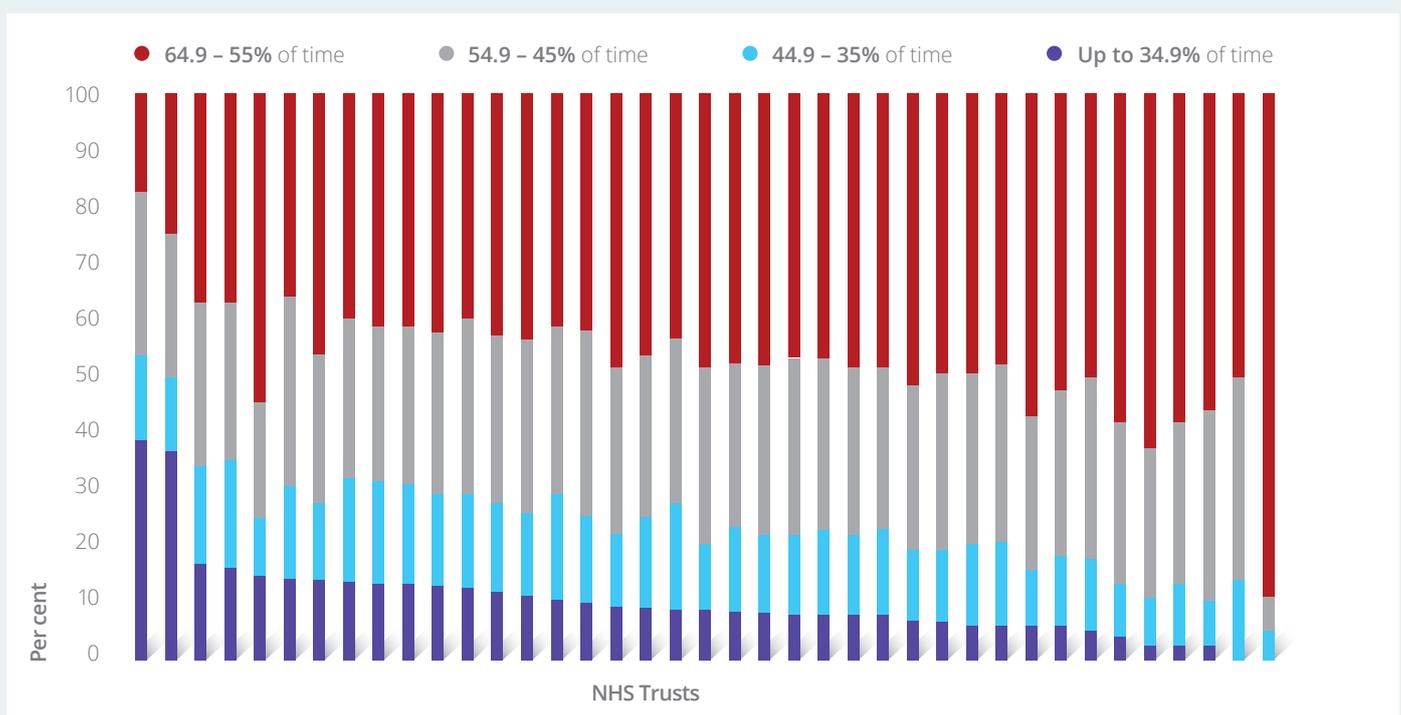
Two INR values higher than 5.0 within the past six months	1,565
One INR value higher than 8.0 within the past six months	798
Two INR values less than 1.5 within the past six months	6,210
TTR less than 65 per cent	29,305

More granular data provided on TTR scores show that there are 29,305 patients with a TTR of less than 65 per cent who are not receiving the full benefits of anticoagulation.^{12, 47} Those patients with a TTR of less than 40 per cent may not be receiving any benefits of anticoagulation. Any patients in this category, whose TTR is lower than 30 per cent, will be at increased risk of stroke and death compared to if they were not taking warfarin at all.⁴⁷

Recommendation: NHS England and Public Health England should routinely collect INR and TTR data for individual anticoagulation service providers to share with commissioners and providers to inform strategies to improve the quality of anticoagulation control

Patients recorded with sub-optimal anticoagulation control, by TTR ranges (appendix 3)¹³

For Trusts that responded to the FOI request, this chart shows a breakdown of the TTR of patients recorded with sub-optimal anticoagulation control. Within those patients, the proportion of patients with the worst TTR scores (34.9 per cent and below) ranges from 0 to 39 per cent between Trusts, indicating that in some Trusts there is a significant proportion who are not receiving any of the benefits of anticoagulation and may be, in some cases, at increased risk of stroke compared to if they were not taking treatment at all.⁴⁷



Managing sub-optimal anticoagulation treatment

Where poor anticoagulation control is identified in warfarin patients, it is recommended that they are assessed to determine why their INR is unstable. A discussion takes place with their healthcare professional to understand and address possible contributing factors. These include: adherence to the treatment; other illness; interacting drugs; lifestyle factors such as diet and alcohol intake; as well as cognitive impairment.¹⁶ NICE clinical guidelines state that if anticoagulation control cannot be improved, the risks and benefits of alternative therapies, such as a DOAC, should be discussed with the patient.⁶

All anticoagulation services should have clear written protocols in place to support the reassessment of patients who have poor warfarin anticoagulant control.¹ Despite this, only 38 per cent of Trusts responding to the FOI request indicated that they have written clinical protocols in place.¹⁸ A further three confirmed that a protocol is in development.¹⁸ While clinicians should already be adhering to the guidance provided by NICE for reassessing poorly-controlled patients' anticoagulation, a written clinical protocol should be in place to support the reassessment of patients who have poor warfarin anticoagulant control.

Recommendation: NHS Trusts should develop clear written clinical protocols to inform healthcare professionals of the procedures for reviewing the anticoagulation of AF patients who demonstrate poor anticoagulation control and are consequently at increased risk of stroke or bleeding

Applying learnings from previous failures of care is a major driver of service improvement and instrumental to instilling accountability amongst Trusts and local commissioners. The national prevention programme aimed at improving outcomes for patients who develop hospital-associated Venous Thromboembolism (VTE) mandated a Root Cause Analysis to be carried out on all cases of hospital-associated VTE.^{48,49} This has increased understanding of the proportion of adverse events that could be prevented, enabled lessons to be learned from individual episodes and identified common themes associated with inadequate VTE prevention.⁴⁹

To understand what actions anticoagulation service providers in secondary care are taking to reduce the proportion of the preventable AF-related strokes, we asked trusts to provide details on root cause analysis of adverse events related to anticoagulation treatment in AF patients undertaken in the past 12 months.

From the results provided by Trusts responding to our FOI requests, six adverse events (AEs) related to anticoagulation were reported.¹⁷ Despite these low numbers, given the number of patients identified as being sub-optimally managed and evidence of the proportion of AF patients being admitted to hospital with a stroke who had poor anticoagulation control, more needs to be done to improve understanding of the reasons why individual people with AF, who are diagnosed and should be receiving treatment, are still being admitted with a stroke, and what interventions may have been missed or causes of sub-optimal anticoagulation management.

Recommendation: The Royal College of Physicians should routinely collect and publish SSNAP audit data on the number of AF-related stroke patients admitted to hospital who are prescribed an anticoagulant and found to have inadequate anticoagulation control, disaggregated by treatment

Recommendations

The information gathered from NHS Trusts providing anticoagulation services adds to existing evidence of scope to improve the management of patients with AF following diagnosis to reduce their risk of stroke. To ensure that the standards of patient care specified in current clinical guidelines are being fully implemented, we have set out the following recommendations aimed at enabling better planning and provision of anticoagulation services through better data collection, reporting systems and support for patients:

- All national policy documents related to the prevention of AF-related stroke should be updated to make explicit that failure to prescribe an effective anticoagulant should be regarded as a 'never event'
- NHS England and Public Health England should publish annual data on progress in increasing the proportion of AF patients who are offered and started on appropriate NICE-approved anticoagulant treatment
- The NICE clinical guideline (CG180) should be updated to include a clear specification of the information, education and support materials that anticoagulation service providers should be routinely offering to AF patients
- For all suitable warfarin patients, it should be recorded in their patients notes whether they have been offered to self-monitor and/or self-manage their anticoagulation, and where these have not been offered, an explanation should be provided
- NHS England and Public Health England should routinely collect INR and TTR data for individual anticoagulation service providers to share with commissioners and providers to inform strategies to improve the quality of anticoagulation control
- NHS Trusts should develop clear written clinical protocols to inform healthcare professionals of the procedures for reviewing the anticoagulation of AF patients who demonstrate poor anticoagulation control and are consequently at increased risk of stroke or bleeding
- The Royal College of Physicians should routinely collect and publish SSNAP audit data on the number of AF-related stroke patients admitted to hospital who are prescribed an anticoagulant and found to have inadequate anticoagulation control, disaggregated by treatment

Appendix 1

List of FOI requests submitted to trusts

The data required for the fulfilment of these requests are routinely collected and stored on the DAWN, INRStar and ProTime software programmes to support the provision of anticoagulation services.

1. Please confirm or deny whether your NHS Trust collects data on the number of patients diagnosed with atrial fibrillation who are treated with warfarin by i) gender and ii) age group.
 - a. If confirmed, please provide the number of i) male and ii) female patients
 - b. If confirmed, please provide the number of patients aged i) below 45 years old ii) 45-54 years old, iii) 55-64 years old, iv) 65-74 years old, v) 75-84 years old and vi) 85 years old and above
2. Please confirm or deny whether your NHS Trust collects data on the time in therapeutic range (TTR) of patients diagnosed with atrial fibrillation who are treated with warfarin.
 - a. If confirmed, please provide details of the number of patients with a TTR (calculated over a maintenance period of at least 6 months while excluding those initiated within the last 6 weeks, as per NICE Clinical Guideline 180 (CG180)) of i) 64.9-55 per cent, ii) 54.9-45 per cent, iii) 44.9-35 per cent and iv) 34.9 per cent and below.
3. Please confirm or deny whether your NHS Trust collects data on the International Normalised Ratio (INR) values of patients diagnosed with atrial fibrillation who are treated with warfarin.
 - a. If confirmed, please provide details of number of patients within the past six months recorded with i) two INR values higher than five, ii) one INR value higher than eight, or iii) two INR values less than 1.5.
4. Please confirm or deny whether your NHS Trust collects data on the frequency of blood tests for purposes of INR readings of patients diagnosed with atrial fibrillation.
 - a. If confirmed, please provide details of the average interval between blood tests for INR readings.
5. Please confirm or deny whether your NHS Trust collects data on the number of patients diagnosed with atrial fibrillation who are treated with warfarin and self-monitoring or self-managing their anticoagulation therapy.
 - a. If confirmed, please provide the number of patients diagnosed with atrial fibrillation who are treated with warfarin who are i) self-monitoring and receiving dosing instructions from a healthcare professional; and ii) self-managing their anticoagulation.
6. Please confirm or deny whether your NHS Trust has conducted a root cause analysis of adverse events related to anticoagulation treatment in atrial fibrillation patients.
 - a. If confirmed, please provide details of any root cause analysis of adverse events related to anticoagulation treatment in atrial fibrillation patients in the last 12 months.
7. Please confirm or deny whether your NHS Trust has written clinical protocols in place for reassessing patients diagnosed with atrial fibrillation who have poor warfarin anticoagulation control (as defined by NICE CG180) to determine why their TTR/INR are unstable.
 - a. If confirmed, please provide evidence of the protocol(s).
8. Please confirm or deny whether your NHS Trust has information, education and support tools available for patients diagnosed with atrial fibrillation to help them understand their treatment options and support adherence.
 - a. If confirmed, please provide evidence of the information, education and support tools that you use.

Appendix 2

Data on the International Normalised Ratio (INR) values of patients diagnosed with atrial fibrillation (AF) who are treated with warfarin

In total, 52 NHS Trusts indicated that they collect data on the INR values of AF patients treated with warfarin. However, only 45 of these Trusts were able to provide a complete breakdown of these INR values, with the remaining Trusts indicating that the data are unavailable in the format requested in the audit.

Number of patients within the past six months recorded with...

NHS Trust	Two INR values higher than five	One INR values higher than eight	Two INR values less than 1.5
Airedale NHS Foundation Trust	17	10	36
Ashford and St Peter's Hospitals NHS Foundation Trust	13	8	59
Barts Health NHS Trust	n/a	n/a	n/a
Bedford Hospital NHS Trust	6	≤2	34
Blackpool Teaching Hospitals NHS Foundation Trust	31	32	198
Bolton NHS Foundation Trust	8	0	67
Brighton and Sussex University Hospitals NHS Trust	≤5	≤5	6
Buckinghamshire Healthcare NHS Trust	24	≤5	58
Central Manchester University Hospitals NHS Foundation Trust	1	1	30
Countess Of Chester Hospital NHS Foundation Trust	11	7	65
Derbyshire Community Health Services NHS Foundation Trust	n/a	n/a	n/a
East Kent Hospitals University NHS Foundation Trust	0	1	11
East Lancashire Hospitals NHS Trust	19	12	125
Epsom and St Helier University Hospitals NHS Trust	13	22	115
Frimley Health NHS Foundation Trust	7	7	20
George Eliot Hospital NHS Trust	11	9	87
Great Western Hospitals NHS Foundation Trust	64	37	159
Hinchingbrooke Health Care NHS Trust	11	4	134
Ipswich Hospital NHS Trust	21	23	119
Kingston Hospital NHS Foundation Trust	73	22	177
Lewisham and Greenwich NHS Trust	n/a	n/a	n/a
Medway NHS Foundation Trust	n/a	n/a	n/a
Mid Cheshire Hospitals NHS Foundation Trust	37	8	178
Mid Yorkshire Hospitals NHS Trust	44	25	237
North Bristol NHS Trust	3	0	6
Northern Devon Healthcare NHS Trust	≤5	≤5	20
Northumbria Healthcare NHS Foundation Trust	486	58	1054
Nottingham University Hospitals NHS Trust	45	21	229
Oxford University Hospitals NHS Foundation Trust	49	44	186
Pennine Acute Hospitals NHS Trust	11	0	208
Poole Hospital NHS Foundation Trust	15	7	110
Royal Berkshire NHS Foundation Trust	20	28	101
Royal Free London NHS Foundation Trust	31	4	193
Royal Liverpool and Broadgreen University Hospitals NHS Trust	39	8	497
Salford Royal NHS Foundation Trust	n/a	24	n/a
Sandwell and West Birmingham Hospitals NHS Trust	16	9	74
Sheffield Teaching Hospitals NHS Foundation Trust	17	5	84
St Helens and Knowsley Hospitals NHS Trust	9	17	32
Stockport NHS Foundation Trust	11	15	86
Surrey and Sussex Healthcare NHS Trust	7	10	61
The Dudley Group NHS Foundation Trust	152	87	276
The Hillingdon Hospitals NHS Foundation Trust	44	24	233
The Princess Alexandra Hospital NHS Trust	15	40	n/a
The Rotherham NHS Foundation Trust	1	0	2
The Royal Wolverhampton NHS Trust	31	28	112
The Whittington Hospital NHS Trust	14	8	n/a
University Hospitals of Morecambe Bay NHS Foundation Trust	34	31	117
University Hospitals of North Midlands NHS Trust	29	30	299
West Hertfordshire Hospitals NHS Trust	12	17	90
West Suffolk NHS Foundation Trust	6	2	25
Western Sussex Hospitals NHS Foundation Trust	45	35	161
Wye Valley NHS Trust	2	1	39

*Figures were provided by Trusts in this format in accordance with their data protection policies. As such, we have considered these figures as the highest value

Appendix 3

Data on the time in therapeutic range (TTR) of patients diagnosed with atrial fibrillation (AF) who are treated with warfarin

In total, 53 NHS Trusts indicated that they collect data on the TTRs of AF patients treated with warfarin. However, only 39 of these Trusts were able to provide a complete breakdown of these TTRs, with the remaining Trusts indicating that the data are partially or wholly unavailable in the format requested in the audit. Therefore, only the completed data below have informed the chart on page 11.

Number of patients with a TTR (calculated over a maintenance period of at least six months while excluding those initiated within the last six weeks, as per NICE Clinical Guideline 180 (CG180)) of...

NHS Trust	64.9 – 55%	54.9 – 45%	44.9 – 35%	34.9% and below
Airedale NHS Foundation Trust	168	96	50	54
Ashford and St Peter's Hospitals NHS Foundation Trust	184	111	48	39
Barts Health NHS Trust	89	61	32	27
Bedford Hospital NHS Trust	87	39	14	n/a
Blackpool Teaching Hospitals NHS Foundation Trust	537	326	165	107
Bolton NHS Foundation Trust	123	59	20	10
Brighton and Sussex University Hospitals NHS Trust	≤5*	≤5*	≤5*	≤5*
Buckinghamshire Healthcare NHS Trust	320	233	152	84
Central Manchester University Hospitals NHS Foundation Trust	8	13	7	18
Countess Of Chester Hospital NHS Foundation Trust	163	77	28	19
Derbyshire Community Health Services NHS Foundation Trust	n/a	n/a	n/a	n/a
East Kent Hospitals University NHS Foundation Trust	8	8	4	12
East Lancashire Hospitals NHS Trust	354	276	146	121
Epsom and St Helier University Hospitals NHS Trust	116	84	64	
Frimley Health NHS Foundation Trust	89	57	21	18
Gateshead Health NHS Foundation Trust	n/a	n/a	n/a	n/a
George Eliot Hospital NHS Trust	188	118	82	61
Great Western Hospitals NHS Foundation Trust	n/a	n/a	n/a	n/a
Hampshire Hospitals NHS Foundation Trust	386	293	181	181
Heart Of England NHS Foundation Trust	286	268	132	118
Hinchingbrooke Health Care NHS Trust	255	158	39	12
Ipswich Hospital NHS Trust	481	297	140	85
Kingston Hospital NHS Foundation Trust	n/a	n/a	n/a	n/a
Leeds Teaching Hospitals NHS Trust	580	370	362	
Mid Cheshire Hospitals NHS Foundation Trust	570	349	160	80
Mid Yorkshire Hospitals NHS Trust	476	289	150	82
North Bristol NHS Trust	15	1	1	0
Northern Devon Healthcare NHS Trust	17	12	≤5*	0
Nottingham University Hospitals NHS Trust	414	265	119	79
Oxford University Hospitals NHS Foundation Trust	512	335	163	73
Pennine Acute Hospitals NHS Trust		1505		
Poole Hospital NHS Foundation Trust	198	82	28	10
Royal Berkshire NHS Foundation Trust	471	296	122	54
Royal Free London NHS Foundation Trust	503	312	170	110
Royal Liverpool and Broadgreen University Hospitals NHS Trust	594	402	257	200
Sandwell and West Birmingham Hospitals NHS Trust	275	208	140	126
Sheffield Teaching Hospitals NHS Foundation Trust	156	101	47	29
St Helens and Knowsley Hospitals NHS Trust	n/a	n/a	n/a	n/a
Stockport NHS Foundation Trust	311	202	100	58
Surrey and Sussex Healthcare NHS Trust	149	107	52	41
Tameside Hospital NHS Foundation Trust	n/a	n/a	n/a	n/a
The Dudley Group NHS Foundation Trust	626	415	276	214
The Hillingdon Hospitals NHS Foundation Trust		656		174
The Princess Alexandra Hospital NHS Trust	508	295	119	75
The Rotherham NHS Foundation Trust	21	8	4	6
The Royal Wolverhampton NHS Trust		379		
The Whittington Hospital NHS Trust	n/a	n/a	n/a	n/a
University Hospitals Bristol NHS Foundation Trust	111	61	28	13
University Hospitals Of Morecambe Bay NHS Foundation Trust	183	92	34	≤10*
University Hospitals of North Midlands NHS Trust	637	393	164	97
West Hertfordshire Hospitals NHS Trust	220	155	103	79
Western Sussex Hospitals NHS Foundation Trust	554	378	239	129
Wye Valley NHS Trust	94	74	35	24

*Figures were provided by Trusts in this format in accordance with their data protection policies. As such, we have considered these figures as the highest value

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